

Memo Of Meeting

Date: February 21, 2002

Representing Quality Systems International, Inc., Unit of IBS America, Inc.:

Mr. Dan Riordan, Director, Product Management
Mary V. McAfee, Director of Implementation

Representing FDA:

Dennis M. Dignan, Consumer Safety Officer, Center For Food Safety and Applied Nutrition
Aydin Orstan, Consumer Safety Officer, Detailee to Office of Enforcement, Office of the Associate Commissioner For Regulatory Affairs
Paul J. Motise, Consumer Safety Officer, Office of Enforcement, Office of the Associate Commissioner For Regulatory Affairs

The meeting was held at the request of the QSI representatives to discuss their products in the context of 21 CFR Part 11. We explained that the meeting was an information exchange and that FDA does not approve or disapprove of products and services that enable the regulated industries to comply with FDA regulations.

The representatives explained that QSI is now a unit of IBS America, Inc. and is engaged in producing electronic document management software, with a focus on compliance management applications (including document control, training, equipment calibration, and corrective action reports). The firm has customers around the world, including food and medical device manufacturers.

During the meeting the QSI representatives gave us a brief demonstration of their document control software, a product that works in conjunction with Lotus Notes on Windows, Unix and Linux computing platforms. The product includes different database modules to handle various portions of an electronic record lifecycle.

The QSI representatives demonstrated how their software handles the controlled time sequenced development of electronic records and how the system can generate electronic copies of electronic records that FDA could audit and copy.

The QSI representatives demonstrated the audit trail capabilities of their software. The audit trail records the date and time when human operators create, revise, delete, or submit a record for changes to units within an organization. Records marked for deletion are preserved in several locations,

thus preventing unauthorized record destruction. The audit trail function cannot be turned off.

Regarding system validation, the representatives said they accept customer audits of their software development activities and provide test scripts to customers. The representatives explained that the product source code ships with the application; persons who have the Lotus Notes application can read the source code.

Electronic signatures take the form of two passwords that are entered after an operator enters a Lotus Notes log on id code and password. By default, passwords must be at least 8 characters long and cannot be reused. Electronic signature manifestations take the form of the signer's printed name, date and time of signing and what the signature means.

The system allows for web based read only access to records in the system database.

The representatives provided us with a series of product data sheets that are attached as PDF files.

The meeting lasted about two hours.

The QSI System for Document Control provides all the templates and examples needed to complete a well structured Quality Manual and to create Procedures, Work Instructions, Specifications, Quality Plans and Process Description documents. Features include multi-level access security, electronic signatures, revision control and automated document status updates. Document review and approval workflow across the network can be either sequential or parallel. Activities associated with every document are automatically recorded in the history section. Document archiving is automatic.



OPERATIONAL CONTROLS

For maximum efficiency QSI software provides controls for every aspect of the operation, including: electronic signatures with up to two back-up approver selections for each approver, customer definable numbering options, automated alpha or numeric choice for versioning, user definable text headers for all documents, document review and audit scheduling, automated status tracking of each document, and templates for Procedures, Work Instructions, Process Descriptions, Specifications and Quality Plans.

PROCESS CONTROLS

Beyond operational controls, controls are in place to monitor the process of tasks. Back-up approvers receive automatic notification when documents are not approved by primary approvers within a user definable time period. Missed deadlines for document approvals, document change requests and document audits can be escalated to up to three levels of management. There are automatic electronic notifications and distribution of documents upon approval. The controls provide reviews and predefined document audits with automatic notification to document owners of impending audit dates, user definable release scheduling of approved documents to allow for training, and automatic updating of training records prior to document release. For multi-site installations, duplicate document numbering alerts are sent. To ensure accuracy, final approval messages are sent with "comments" capability and

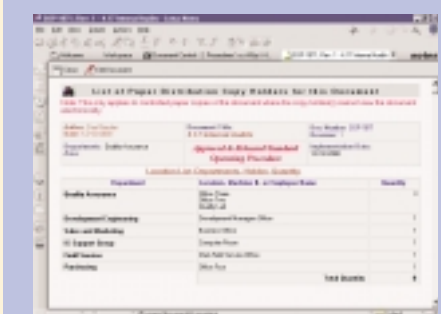
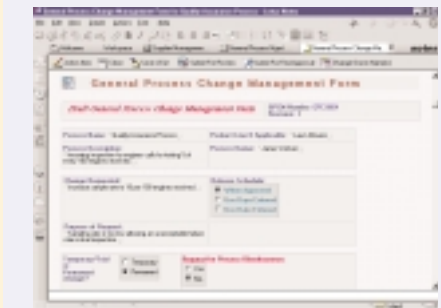
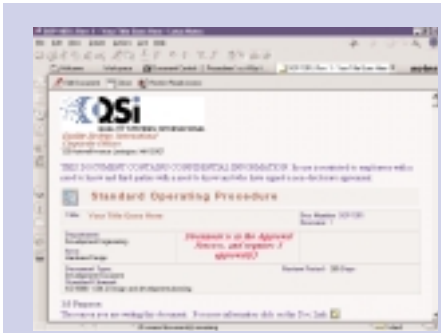
there is an option to notify associated (linked) document owners of changes or new releases. The system allows users to display all documents associated with each individual document for easy access and management.

SECURITY CONTROLS

These controls provide selectable approver allowances with 7 levels of database security. Process security prevents documents from being modified in the final approval process. There is selective read access restriction on a per document basis, and if a document is edited, there is an automatic status change alert.

PROCESS WORKFLOW

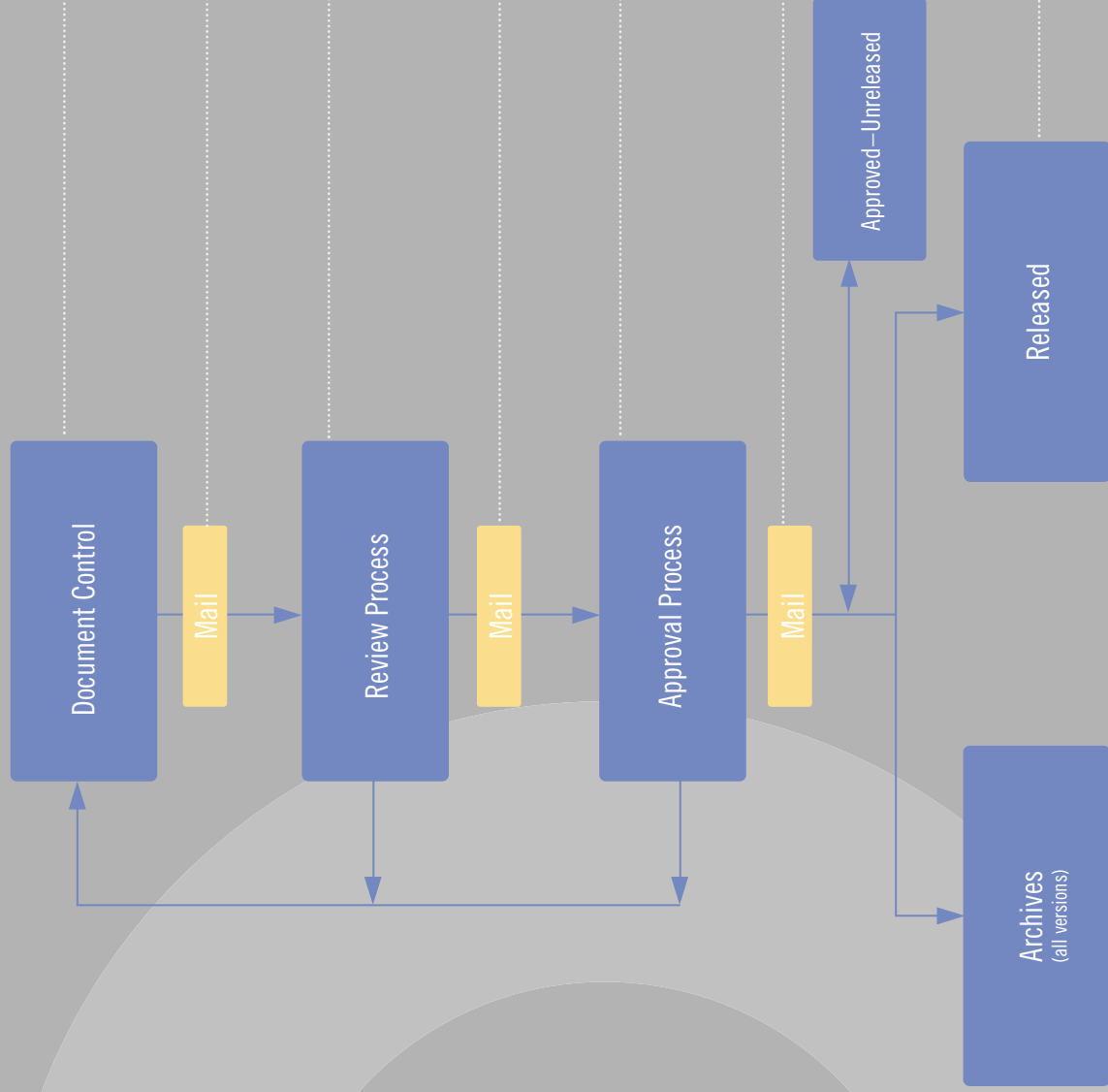
There is a choice of two approval processes, review and final approval. With this flexible workflow, serial or parallel approval is selectable for each document. Upon final approval documents automatically move and replace earlier versions in the Released Documents data base. Every released document is automatically archived and stored. Users can define the release of approved documents to allow for training.



“...Implementing a robust Document Control system for our ISO 9001 certification process would have been extremely difficult without using System 9000. In fact, we have also implemented the ISO 14000 and QS 9000 options... With all the benefits that we have gained from the use of System 9000, we are definitely strong advocates of this system.”

Jerome Lofton, Jr., Motorola Energy Systems Group

QSI System for Document Control



DOCUMENT CONTROL

Create new documents or modify existing ones.
Select: document type, numbering system, audit period, release schedule, serial or parallel workflow, send for review on final approval, approver allowances, standard or customer specific form layouts.

MAIL

When a document is sent for review all reviewers are automatically notified.

REVIEW PROCESS

An optional review process allows reviewers to approve documents or disapprove with recommendations.
A signature countdown is maintained and messages are automatically sent to reviewers and authors for each approval or disapproval.

MAIL

When a document is sent for final approval, all approvers are automatically notified.

APPROVAL PROCESS

During the approval process documents cannot be edited, but may be approved or disapproved with comments to the author.
Document status is automatically tracked and a signature countdown is maintained.

MAIL

Once approved all members of the distribution list are automatically notified.

APPROVED—UNRELEASED

A holding area is provided for documents with a delayed release date to allow for document training prior to release. Automatic messages are sent to those employees requiring training.
The Approved-Unreleased Documents database requires interaction with the Employee Training database.

RELEASED

The latest release automatically replaces the previous version.

ARCHIVES

Contains copies of all approved and released versions of all documents.

QSI Reports

A great reporting tool for System 9000 which gives you the information you need to monitor and manage your compliance system in:

- **Charts,**
- **Graphs, and**
- **Drill-down.**

When faced with a business challenge, you don't want to search through categorized views of data trying to figure out what is happening in your quality system. You want fast, intuitive access to your data, powerful ad hoc analysis and reliable reports that can help you:

- identify costs graphically
- target problem areas
- track improvement process
- recognize areas of opportunity

QSI Reports is the solution. It provides the foundation to help you demonstrate the process of continual improvement. Use the sample reports provided or create your own to address your business needs now and in the future. All of the reports can be made available to tens or thousands of people throughout your enterprise.

QSI Reports is a total client-server solution that delivers data intuitively from System 9000 databases. This data is knowledge that your company's employees can use to create powerful ad hoc analysis and save the results as charts and graphs. These reports can include drill-down to source information and traffic lighting to highlight trouble spots.

Architecture

QSI Reports for System 9000 has two key components:

QSI Cuber™ defines Tasks which create management information from System 9000 data.

QSI KAS™, a Knowledge Action System, provides easy-to-use graphical ad hoc query and drill-down and allows you to read and manipulate report formats and parameters.

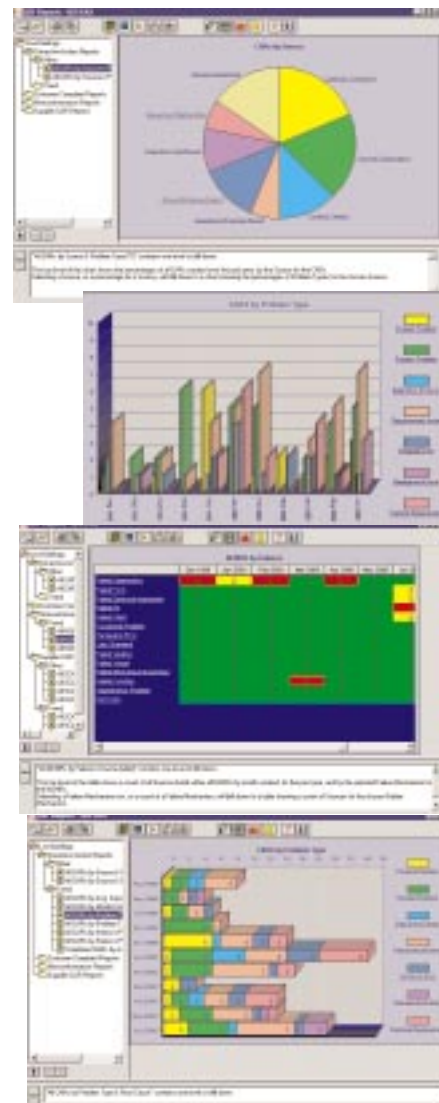
How It Works

The solution is delivered as a single Notes/Domino database and uses the client/server architecture of Notes/Domino for delivery and security. The QSI Cuber Task Manager creates consolidation tasks to run against specified System 9000 databases, locally or on a Domino server. You can then view these as meaningful, graphical management information.

QSI Cuber can use existing views to specify report Tasks that include slicing and drill-down. Each report is created and stored as a table in a separate Notes document, so no new views need to be added to the database.

QSI Cuber agents update the report documents so they can be virtually 'real-time' or month-end reports - it's up to you.

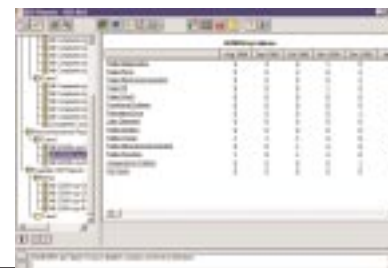
QSI KAS for System 9000 reads the report documents and allows for dynamic graphing, traffic lighting and commentary.



QSI Reports

QSI Cuber - Product Features

- **Multidimensional Information** - Data seen from different perspectives - by product, by region, by month... whatever you need!
- **Data Calculations** - Percentages, calculations, totals or write your own formulas (i.e., Total Cost/No. of Complaints)
- **Simple User Interface** - Report generation is easy-to-learn and easy-to-use
- **Time Saver** - Set up a query once to update reports automatically with 'up-to-the-minute' data
- **Data Hierarchies** - Drill-down from top level to detail information
- **Flexibility** - Read any System 9000 data presented in a view
- **Date Calculations** - Automatically set up date drill-down into years, quarters, months, weeks, etc.



QSI KAS Product Features

- **Drill-down** - View hierarchical information to identify the source of suspected quality or other business problems
- **Chart Templates** - An extensive library of chart and table templates enable you to locate the best style for reports
- **Chart Customization** - Right-click the report to easily change the display
- **Exception Reporting** - Add traffic lights to reports to identify 'hot spots' requiring immediate attention
- **Ad Hoc Query** - Answer specific business questions using slice and dice capabilities
- **Simple Integration** - QSI reports are fully compatible with other Windows applications
- **Effortless Distribution** - Deliver the charts and graphs to everyone using your existing Notes infrastructure
- **Add Commentary** - Include user insights to help identify opportunities for business improvement and highlight issues before they become problems
- **Privacy** - Anyone can save a report in a private folder

Performance

QSI Cuber provides exceptional performance benefits by minimizing database storage in two ways:

- Information is stored in Notes documents which eliminates the need for additional Notes views.
- Data is consolidated.

Reduced Server Loading - Reports are pre-calculated and stored on the server, so no on-line queries are being made against the live database.

Consolidation Speed - QSI Reports can create a report from a database in minutes (dependent on the speed of processor, amount of available memory and/or the complexity of the report set specified).

Compatibility with other Windows Applications

Copy QSI KAS screens into any other Windows applications (Freelance Graphics, Power Point or Word, for example). Or copy QSI Cuber data onto the Windows clipboard and paste it into spreadsheets.

Security

Notes/Domino replication and access control means that every user sees information based on who they are (their user ID) and what they do (the roles they play) in a secure, controlled environment.

Technical Requirements

QSI KAS for Lotus Notes Client

Operating System

Windows 95
Windows 98
Windows 2000
Windows NT 4.0

Lotus Notes/Domino

Notes 4.6 and above

Disk Space

4 Mb

Memory Requirements

16 Mb

QSI Cuber Server

Operating System

Windows 95
Windows 98
Windows 2000
Windows NT 4.0

Lotus Notes/Domino

Notes 4.6 and above

Disk Space

250 Mb
(1 Gb recommended)

Memory Requirements

32 Mb
(128 Mb recommended)

Lotus Notes and Domino are trademarks of Lotus Development Corporation. Cuber and KAS are trademarks of Show Business Software Ltd.



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